MAR 2 8 2000

K000660

ATTACHMENT 4

510(k) Summary

Date February 25, 2000

Contact
Cedric Navarro
Quality Asssurance/Regulatory Affairs Manager
Medical Data Electronics
12720 Wentworth Street
Arleta, California 91331
Telephone: 818-768-6411
Telefax: 818-768-4197
Email: cnavarro@emailmde.com

Device Name ESCORT II+ 400 Series (ESCORT Prism) Monitor

Common Name Patient Monitor, Vital Signs Monitor
May Include Options:

Cardiac Monitor	Carbon Dioxide Analyzer
Breathing Frequency Monitor	Cardiac Output Computer
Invasive Blood Pressure	Recorder
Temperature	RF Physiological Transmitter/Receiver
Noninvasive Blood Pressure	Defibrillator
Pulse Oximetry	External Pacer

Classification The classification names and classifications of the Options available for the ESCORT II+ 400 Series (ESCORT Prism) monitors are as follows:

Option	Classification Number	Class
Cardiac Monitor	870.2300	II
Breathing Frequency Monitor	868.2375	II
Invasive Blood Pressure	870.1110	II
Temperature	880.2910	II
Noninvasive Blood Pressure	870.1130	II
Pulse Oximetry	870.2700	II
Carbon Dioxide Analyzer	868.1400	II
Cardiac Output Computer	870.1435	II
Recorder	870.2810	II
RF Physiological Transmitter/Receiver	870.2910	II
Defibrillator	870.5300	II
External Pacer	870.3600	III

Predicate Device	ESCORT® II+ 400 Series (ESCORT Prism™) Monitor
Device Description	The modified ESCORT II+ 400 Series (ESCORT Prism) monitor is identical to the currently marketed device with the exception of the Capnography Options available. The predicate device incorporates Pryon technology, utilizing a sidestream sampling flow rate of 150cc/minute. The modified device, incorporating Oridian technology, utilizes a sidestream sampling flowrate of 50 cc/minute.
Indications For Use	The Medical Data Electronics ESCORT II+ 400 Series Monitor is a portable patient monitor intended to be used for monitoring vital signs of critically ill adult, pediatric and neonatal patients in the hospital environment.
Technological Characteristics	The modified ESCORT II+ 400 Series (ESCORT Prism) has the same technological characteristics as the predicate device with the exception of the type of signal processing utilized for capnographic patient information. The predicate device uses Pryon capnographic technology. The Pryon option requires a sidestream sampling flowrate of 150cc/minute and special moisture-handling filters for proper operation. The modified device uses Oridian capnographic technology. The Oridian option requires a lower flowrate and does not require special filters for moisture-handling.
Testing	Testing of the modified ESCORT II+ 400 Series (ESCORT Prism) monitors was conducted by MDE to ensure mitigation of hazards. V&V testing and testing of the modified device to safety standards are exactly the same as those conducted on the predicate device.
Conclusions	Medical Data Electronics, in accordance with the FFDCA and 21 CFR Part 807 and data included in this premarket notification, concludes that the modified ESCORT II+ Model 400 Series (ESCORT Prism) Monitor is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2000

Mr. Cedric Navarro
Medical Data Electronics, Inc.
12720 Wentworth Street
Arleta, CA 91331-4329

Re: K000660
ESCORT® II+ 400 Series Monitors (ESCORT Prism™)
Regulatory Class: III (three)
Product Code: 74 DRO
Dated: February 25, 2000
Received: February 28, 2000

Dear Mr. Navarro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

Indications for Use Statement

510(k) Number (if known): ~~K961198~~ K000660

Device Name: ESCORT II+ 400 Series (ESCORT Prism) Monitor

Indications for Use:

The Medical Data Electronics ESCORT II+ 400 Series Monitor is a portable patient monitor intended to be used for monitoring vital signs of critically ill adult, pediatric and neonatal patients in the hospital environment.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000660

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)